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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,741	07/07/2003	Kimberly A. Anderson	S16.12-0136	6207
27367 7590 10/31/2008 WESTMAN CHAMPLIN & KELLY, P.A. SUITE 1400 900 SECOND AVENUE SOUTH MINNEAPOLIS, MN 55402-3244				
EXAMINER				
GANESAN, SUBA				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
10/31/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/614,741

**Applicant(s)**

ANDERSON ET AL.

**Examiner**

SUBA GANESAN

**Art Unit**

3774

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-22-24, 26, 27 and 30-43 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-22-24, 26-27, 30-34, 36-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/2008 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 9/30/2008 have been fully considered but they are not persuasive. Applicants amendment including a *separate* reinforcement does not overcome the previously cited prior art. Separating the current reinforcement from the frame would have been obvious to one of ordinary skill in the art at the time the invention was made for the purpose of providing variable suture pad options to a surgeon (for example, different sizes, shapes or densities). Alternatively, adding a reinforcement on top of the suture pad of Johnson would have further been obvious for the purpose of providing extra reinforcement.

### ***Allowable Subject Matter***

3. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 20, 22-24, 26-27 and 30-34, 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (5,449,384) in view of Williamson IV et al (6,402,780).

6. Johnson discloses a method for attaching a porcine heart valve prosthesis comprising inserting fasteners 708, 710, 712 (sutures) through the prosthesis and through an aortic wall 700 (fig. 17). The prosthesis comprises leaflets 724, 726, 728 with commissure supports 210, 212, 214 and reinforcements 220, 222, 218 positioned along an inner surface of at least one of the commissure supports. The reinforcements 220, 222, 218 are unitary pledgets or suture pads, wrapped around the commissure supports. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided separate suture pads or additional suture pads along the inner surface as suggested by Johnson (col. 5 lines 50-53), the motivation being: providing a greater surface area to distribute the stresses of the attachment to the native annulus. Separating the current reinforcement from the frame would have been obvious to one of ordinary skill in the art at the time the invention was made for the purpose of providing variable suture pad options to a surgeon (for example, different sizes, shapes or densities). Alternatively, adding a reinforcement (an

extra pledget) on top of the suture pad of Johnson would have further been obvious for the purpose of providing extra reinforcement and support.

7. The reinforcements include an aperture (Fig. 3). The fastener is inserted through the aperture and into the aortic wall (See fig. 17). It would have been obvious to employ the suturing method including pledgets as disclosed by Johnson with a stentless prosthetic valve (for example Quintero, 5,197,979), since such modification would have been a combination of prior art elements yielding predictable results.

8. However Johnson fails to show fastener having a head and barbed tip. Williamson IV et al teaches the use of a fastener having a head and sharp barbed tip (e.g. Fig. 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of a fastener having a head and tip, as taught by Williamson IV et al, to a method as per Johnson, the fasteners of Williamson IV et al being capable of connecting vascular tissues or implants to tissues (see abstract) in situations where the use of sutures would be more difficult (col. 2, lines 5-18). See Williamson IV for various fastener types.

9. With respect to claim 34, the reinforcement of Johnson includes pledgets or suture pads along the outer surface of the prosthesis (see fig. 16-17). The fasteners are inserted along a curvilinear path (at the three commissure locations)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./  
Examiner, Art Unit 3774  
/William H. Matthews/  
Primary Examiner, Art Unit 3774